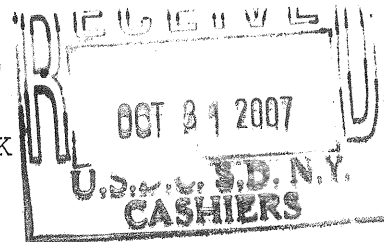


07 CIV 9669

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK



-----X
HAZEL JANE CLARK and BRIAN CLARK, : Civil Action No.
: :
: 07 CV ____
Plaintiffs, :
: :
v. : COMPLAINT
: :
NOVARTIS PHARMACEUTICALS :
CORPORATION, : JURY TRIAL DEMANDED
: :
Defendant. :
: :
-----X

Plaintiffs Hazel Jane Clark ("Jane Clark") and Brian Clark (collectively "Plaintiffs"), by their attorneys, for their Complaint against defendant Novartis Pharmaceuticals Corporation ("Novartis" or "Defendant"), allege:

1. This is a civil action for damages suffered by Plaintiffs as a result of Jane Clark being prescribed and injected with Defendant's drug Aredia.

PARTIES

2. Plaintiffs are citizens and residents of the State of California, residing in Vacaville, California.

3. At all times herein mentioned, Defendant was and is a Delaware corporation, with its principal place of business at One Health Plaza, East Hanover, New Jersey 07936-1080.

4. At all times herein mentioned, Defendant did business in the States of New York and California.

JURISDICTION

5. This Court has original jurisdiction over this action under 28 U.S.C. § 1332, in that the amount in controversy exceeds seventy five thousand dollars (\$75,000.00) and Plaintiffs are citizens of a State which is different from the State where defendant is incorporated and has its principal place of business.

FACTUAL BACKGROUND

6. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

7. Aredia is the brand name of pamidronate, which is in a class of prescription drugs called bisphosphonates. Aredia is administered intravenously and/or by injection.

8. Aredia was approved by the United States Food and Drug Administration for treatment of hypercalcemia and bone metastases.

9. The product literature prepared by Novartis and circulated to physicians for use in prescribing the drug contained no warning about osteonecrosis of the jaw or other bone structure.

10. In 2002 or before, Defendant received information from a physician that several of the physician's patients who were given Aredia were diagnosed with osteonecrosis of the jaw and that he believed a causal relationship existed between the use of Aredia and osteonecrosis of the jaw.

11. Another group of physicians published a report about patients being diagnosed with osteonecrosis of the jaw after being given Aredia and Zometa, another bisphosphonate designed and manufactured by Defendant. The report said, "the jaw complications presented in this review have had a major negative effect on the quality of daily life for each of these patients" and determined that "bisphosphonates may be at least partially responsible." Ruggiero, et al., "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 Cases," Journal of Oral and Maxillofacial Surgery, vol. 62, p. 533 (2004).

12. Defendant sent warnings to physicians regarding the risk of osteonecrosis of the jaw with the use of Aredia and Zometa in September 2004 and May 2005.

13. Jane Clark was prescribed and given Aredia.

14. As a result of being given and/or injected with Aredia, Jane Clark developed osteonecrosis of the jaw.

15. As a result of being given and/or injected with Aredia Jane Clark suffered compensable injuries, including but not limited to the following:

- a. severe and permanent physical and medical injuries and associated disabilities;
- b. severe past and future pain and suffering;
- c. severe past and future mental anguish;
- d. loss of enjoyment of life;
- e. increased risk of health problems;
- f. past and future medical care and monitoring; and
- g. loss of past and future income.

FIRST CLAIM FOR RELIEF

[Strict Product Liability - Design Defect]

16. Plaintiffs incorporate by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

17. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

18. Aredia as designed, manufactured and sold by Defendant was defective in design or formulation in that it was unreasonably dangerous.

19. Aredia as designed, manufactured and sold by Defendant was defective in design or formulation in that its foreseeable risks exceeded the benefits associated with the design or formulation.

20. Aredia as designed, manufactured and sold by Defendant was defective due to inadequate warnings because Defendant knew or should have known that the product created a risk of harm to consumers.

21. Aredia as designed, manufactured and sold by Defendant was defective due to inadequate testing.

22. As the proximate cause and result of the defective condition of Aredia as designed, manufactured and sold by Defendant, Jane Clark was injured.

SECOND CLAIM FOR RELIEF

[Strict Product Liability - Failure To Warn]

23. Plaintiffs incorporate by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

24. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

25. Aredia as designed, manufactured and sold by Defendant was not accompanied by proper warnings regarding possible adverse side effects.

26. Defendant knew or should have known about the possible adverse side effects of Aredia, including osteonecrosis of the jaw.

27. As the proximate cause and result of Defendant's failure to properly warn physicians and consumers, Jane Clark was injured.

THIRD CLAIM FOR RELIEF

[Negligence]

28. Plaintiffs incorporate by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

29. Defendant designed, tested, developed, manufactured, labeled, marketed, distributed and sold Aredia.

30. Defendant had a duty to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia, including a duty to assure that

users, like Jane Clark, did not suffer unreasonable adverse side effects, such as osteonecrosis of the jaw.

31. Defendant failed to exercise reasonable care in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia in that Defendant knew or should have known that Aredia created an unreasonable risk of osteonecrosis of the jaw.

32. Defendant was negligent in designing, testing, developing, manufacturing, labeling, marketing, distributing and selling Aredia.

33. As the proximate cause and result of Defendant's negligence, Jane Clark was injured.

FOURTH CLAIM FOR RELIEF

[Breach of Express Warranty]

34. Plaintiffs incorporate by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

35. Defendant expressly warranted, by and through statements made by Defendant or its authorized agents, that Aredia was safe, effective, and fit for its intended use.

36. Jane Clark, and her agents, relied on the skill, judgment and representations of Defendant.

37. Aredia did not conform to Defendant's express warranties in that it was not safe and fit for its intended use because it caused serious adverse side effects, including osteonecrosis of the jaw.

38. As the proximate cause and result of Defendant's breach of its express warranties, Jane Clark was injured.

FIFTH CLAIM FOR RELIEF

[Breach of Implied Warranty]

39. Plaintiffs incorporate by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

40. Defendant impliedly warranted to Jane Clark, and her agents, that Aredia was of merchantable quality and was safe and fit for its intended use.

41. Jane Clark, and her agents, relied on Defendant's skill and judgment.

42. Aredia was not of merchantable quality or safe and fit for its intended use in that it caused serious adverse side effects, including osteonecrosis of the jaw.

43. As the proximate cause and result of Defendant's breach of its implied warranties, Jane Clark was injured.

SIXTH CLAIM FOR RELIEF

[Loss of Consortium]

44. Plaintiffs incorporate by reference the allegations contained in Paragraphs 1 through 15 of the Complaint as if they were set forth here in full.

45. Brian Clark is, and at all times material hereto was, the husband of Jane Clark.

46. Before being injured as described herein, Jane Clark was able to and did perform all the duties of a spouse, including assisting in maintaining the home and providing companionship, affection, society and support to Brian Clark.

47. As the proximate cause and result of Defendant's conduct identified herein, Jane Clark developed osteonecrosis of the jaw and her ability to perform all the duties of a spouse were impaired.

48. As the proximate cause and result of Defendant's conduct identified herein, Brian Clark has been deprived of, and will in the future continue to be deprived of, the society, companionship and consortium of his wife Jane Clark.

PRAYER FOR RELIEF

WHEREFORE, plaintiffs Jane Clark and Brian Clark respectfully pray for relief and judgment against the defendant as follows:

- (a) compensatory damages in an amount to be determined at trial;
- (b) attorneys' fees, expenses, and costs of this action; and
- (c) for any other relief this Court deems just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiffs respectfully requests a trial by jury on all triable issues pursuant to Rule 38 of the Federal Rules of Civil Procedure.

Dated: New York, New York
October 31, 2007

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